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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,965	11/06/2000	Esmail Kiani-Azarbayjany	MLABS.018C3	8509

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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

11

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/706,965

Applicant(s)

KIANI-AZARBAYJANY ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/8/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 12-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 23 is objected to because of the following informalities. In claim 23, "a" before "input" in line 3 should be "an". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 17-18, 20-21, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,883,055 to Merrick. In regard to claims 17 and 24, Merrick discloses a pulse oximeter probe 28 that includes a light source that emits infrared and red light (Fig. 4 and column 1, lines 14-19 of Merrick), a photodiode (Fig. 4 and column 1, lines 19-23 of Merrick et al.), an active pulse inducement device 32 at a location other than the test site (Fig. 4 of Merrick), and a signal processor (column 1, lines 32-39 of Merrick). In regard to claims 18 and 20, Merrick teaches that the active pulse inducement device causes a periodic change in the form of synchronizing the pressure with the normal blood pulse. (column 2, lines 38-40 of Merrick). In regard to claim 21, Merrick teaches a receptacle with an inflatable bladder in the form of a pressure cuff.

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(Fig. 4 of Merrick). In regard to claim 23, Merrick teaches an oximeter that includes an input and the signal processor. (Fig. 4 and column 1, lines 32-39 of Merrick).

4. Claims 17, 21, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,927,264 to Shiga et al. (cited by Applicant). In regard to claims 17 and 24, Shiga et al. discloses a pulse oximeter probe that includes a light source 5 that emits at least two wavelengths, photodiodes 9₁ and 9₂, an active pulse inducement device 4 at a location other than the test site, and a signal processor 10₁ and 10₂. (Fig. 5 of Shiga et al.). Note that the active pulse inducement device 4 induces a change in the volume of fluid in the fleshy medium while reducing variations in the fleshy medium at the test site. (Fig. 5 of Shiga et al.). In regard to claim 21, Shiga et al. teaches a receptacle with an inflatable bladder in the form of a pressure cuff. (Fig. 5 of Shiga et al.). In regard to claim 23, Shiga et al. teaches an oximeter that includes an input (from photodiodes 9₁ and 9₂) and the signal processor 10₁ and 10₂. (Fig. 5 of Shiga et al.).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,372,135 to Mendelson et al. in view of U.S. Patent 5,007,423 to Branstetter et al. Mendelson et al. discloses a system for obtaining glucose information. (column 1, lines 19-22 of Mendelson et al.). The system includes a lamp (10) that emits a plurality of wavelengths, a pulse inducement device (26, 26'), a detector (32, 32'), and a signal processor (36). (Figs. 3 and 5 of Mendelson et al.). Mendelson et al. does not teach the use of a receptacle that receives the fleshy medium having a temperature variation element for inducing the change in blood flow. Mendelson et al. teaches that the modulation of blood volume can be accomplished in a number of ways. (column 4, lines 32-34 of Mendelson et al.). Mendelson et al. is implying that various methods can be used as the pulse inducement device including methods other than by pressure. Branstetter et al. teaches a temperature element for increasing the blood flow. (column 2, lines 32-47 of Branstetter et al.). Such a device falls within the scope of the devices for creating blood flow modulation as suggested by Mendelson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the temperature element of Branstetter et al. for the pulse inducement device of Mendelson et al. since Mendelson et al. implies that other devices can be used to induce blood flow modulation and Branstetter et al. teaches one such device. Since the temperature element is used as the pulse inducement device, the combination inherently includes a level of inducement below a level that causes significant variation in the optical properties of the fleshy medium. In regard to claim 1, the temperature means would not induce significant variation in the optical properties of

the fleshy medium. The pulse inducement device is operated in a periodic manner. (column 6, lines 11-15 of Mendelson et al.). In regard to claim 12, the pulse inducement device (the temperature element) is operated in a periodic manner which would cause periodic changes in the volume of blood. (column 6, lines 11-15 of Mendelson et al.).

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,372,135 to Mendelson et al. in view of U.S. Patent 5,007,423 to Branstetter et al. as applied to claim 1, and further in view of U.S. Patent 4,883,055 to Merrick. The combination teaches that the pulse inducement device causes periodic changes in the volume of blood. (column 6, lines 11-15 of Mendelson et al.). The combination et al. does not teach what kind of periodic function to use with the pulse inducement device. Merrick teaches a pulse oximeter which analyzes the oxygen saturation of blood. Merrick discloses that applying pressure, which is synchronized with the normal blood pulse is useful for analyzing blood constituents. (column 2, lines 38-40 of Merrick). Such a periodic function falls within the scope of the type of periodic function as suggested by Mendelson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a periodic function that is synchronous with the normal pulse rate as disclosed by Merrick in the pulse inducement device of Mendelson et al. since Mendelson et al. suggests that the pulse inducement device may be used in a periodic manner and Merrick teaches one such periodic manner.

8. Claims 1, 14, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,927,264 to Shiga et al. (cited by Applicant) in view of U.S. Patent 5,372,135 to Mendelson et al.). Shiga et al. discloses a pulse oximeter probe that includes a light source 5 that emits at least two wavelengths, photodiodes 9₁ and 9₂, an active pulse inducement device 4 at a location other than the test site (where fibers 3₁ and 3₂ are contacting the finger), and a signal processor 10₁ and 10₂. (Fig. 5 of Shiga et al.). Note that the active pulse inducement device 4 induces a change in the volume of fluid in the fleshy medium while reducing variations in the fleshy medium at the test site. (Fig. 5 of Shiga et al.). In regard to claim 1, Shiga et al. does not teach the calculation of glucose. Shiga et al. teaches that the invention is used to calculate blood constituents. (claim 1 of Shiga et al.). Shiga et al. also implies that the blood constituents has a broader meaning than just oxygen saturation. (column 2, lines 35-38 of Shiga et al.). Mendelson et al. teaches that glucose is a suitable blood constituent for measurement. (column 3, lines 50-62 of Mendelson et al.). Such a constituent falls within the scope of measuring blood constituents as set forth in Shiga et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to measure glucose concentrations as disclosed by Mendelson et al. since Shiga et al. teaches that the invention is used for measuring blood constituents and Mendelson et al. teaches one such blood constituent. In regard to claim 14 and 16, Shiga et al. teaches a receptacle with an inflatable bladder in the form of a pressure cuff. (Fig. 5 of Shiga et al.). In regard to claim 19, Shiga et al. does not teach repeating the measurement. Mendelson et al. teaches that it is well known in the art to repeat

measurements in a periodic fashion so that the measurements can be averaged in time to improve the overall signal-to-noise ratio. (column 6, line 12-15 of Mendelson et al). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to periodically repeat the measurements since such measurements can be averaged in time so that the overall signal-to-noise ratio is improved.

9. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,883,055 to Merrick as applied to claim 17, and further in view of U.S. Patent 5,372,135 to Mendelson et al. and in view of U.S. Patent 5,007,423 to Branstetter et al. Merrick does not teach a temperature variation element to induce the change in blood flow. Mendelson et al. teaches that the modulation of blood volume can be accomplished in a number of ways. (column 4, lines 32-34 of Mendelson et al.). Mendelson et al. is implying that various methods can be used as the pulse inducement device including methods other than by pressure. Branstetter et al. teaches a temperature element for increasing the blood flow. (column 2, lines 32-47 of Branstetter et al.). Such a device falls within the scope of the devices for creating blood flow modulation as suggested by Mendelson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the temperature element of Branstetter et al. for the pressure inducing means of Merrick since Mendelson et al. implies that other devices can be used to induce blood flow modulation and Branstetter et al. teaches one such device. The pulse inducement

device (the temperature element) is operated in a periodic manner, which would cause periodic changes in the volume of blood, since such measurements averaged in time would improve the overall signal-to-noise ratio. (column 6, lines 11-15 of Mendelson et al.).

Response to Arguments

10. Applicant's arguments with respect to claims 1, 12-14, and 16-24 have been considered but are moot in view of the new ground(s) of rejection. In regard to claim 15, the Applicant did not address the rejection in view of the Mendelson-Branstetter combination previously set forth in the Office Action mailed on 10/10/2003 so the Examiner maintains this rejection as proper without further comment.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

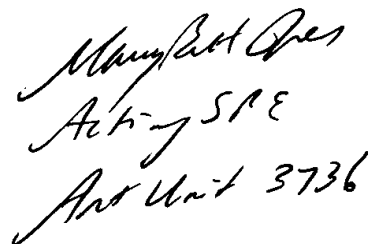
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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